DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

g1439d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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June 20, 2001

WARNING LETTER

NWE-29-01W

VIA FEDERAL EXPRESS

Robert Kofkoff, President
Kofkoff Egg Farms, LLC
17 Schwartz Road
Bozrah, Connecticut 06334

Dear Mr. Kofkoff:

An inspection of your medicated feed mill located in Franklin, Connecticut, conducted by a Food and Drug Administration investigator on March 14-21, 2001, found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds (Title 21, Code of Federal Regulations, Part 225). Such deviations cause medicated feeds being manufactured at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

- Failure to conduct adequate clean-out procedures which could result in unsafe contamination of the finished product. For example, after you manufacture a batch of medicated feed containing penicillin you do not clean your equipment prior to the manufacture of your next batch that may be non-medicated feed.

In addition, you manufacture a medicated feed for replacement chickens that is not approved for such use. This causes the medicated feed to be adulterated within the meaning of Section 501(a)(6) of the Act in that the medicated feed contains a new animal drug, causing the feed to be unsafe within the meaning of Section 512 of the Act as follows:

- Failure to follow the "conditions for use" for penicillin in the manufacture of Type A medicated feed for replacement chickens as specified in 21 CFR 558.460. For example, the medicated feed that you manufacture for replacement chickens for the treatment of chronic respiratory disease contains [redacted] According to 21 CFR 558.460(d)(i), (ii), and (vii) penicillin is used in combination with other drugs to a maximum of 50 g/ton for replacement chickens in lowering the severity of chronic respiratory diseases.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated fees, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these CGMP violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction. Based on the on the result of the March 14-21, 2001 inspection, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein. This letter notifies you of our finding and provides you an opportunity to correct the above deficiencies.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will no recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Bruce, R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Sincerely,

Gail T. Costello
District Director
New England District Office

cc: Hugh J. Mathews, Administrator
Kofkoff Feeds, Inc.
39 Murphy Road
Franklin, Connecticut 06254